

**WHAT IS CLAIMED IS:**

1. An intravaginal device for delivery of a medical instrument to a female patient's uterine cervix, related tissue or near-by anatomical structure, comprising:
  - a. an elongated guide rail which has a distal portion with a distal tip, which has a proximal portion with a free proximal end configured to receive and guide a medical instrument to the patient's uterine cervix, related tissue or near-by anatomical structure; and
  - b. a tissue grasping mechanism secured to the distal portion of the guide rail configured to grasp the patient's uterine cervix to facilitate delivery of the medical instrument over the guide rail to the patient's uterine cervix.
2. The intravaginal device of claim 1 wherein the tissue grasping mechanism comprises:
  - a. a first elongated member which has a proximal section configured for manual manipulation and a distal section with a distal end secured to the distal portion of the guide rail proximal to the atraumatic distal tip; and
  - b. a second elongated member which has a proximal section configured for manual manipulation and a distal section with a tissue grasping distal end and which is pivotally connected to the first elongated member at a pivot point thereon proximally spaced from the distal end of the first elongated member so that the tissue grasping distal end of the second elongated member grasps uterine cervical tissue against the guide rail.
3. The intravaginal device of claim 2 wherein the tissue grasping distal end of the second elongated member is on the same side of the guide rail to which the distal

end of the first elongated member is secured to avoid interfering with advancing a medical instrument over the guide rail.

4. The intravaginal device of claim 2 wherein the manually manipulatable proximal ends of the first and second members are provided with finger grips.

5. The intravaginal device of claim 48 wherein the proximal sections of the first and second members are provided with a locking mechanism to hold the tissue grasping distal end against the patient's uterine cervix.

6. The intravaginal device of claim 1, wherein the atraumatic distal tip has a rounded configuration.

7. The intravaginal device of claim 1, wherein the distal section of the guide rail is formed at least in part of a malleable material.

8. The intravaginal device of claim 7, wherein the malleable material is a soft metal.

9. The intravaginal device of claim 8, wherein the soft metal is silver.

10. The intravaginal device of claim 1 wherein the distal tip is expandable to snugly fit within the patient's cervical canal.

11. The intravaginal device of claim 10 wherein the distal tip is split into bifurcated portions.

12. The intravaginal device of claim 11 wherein the bifurcated portions are curved.

13. The intravaginal device of claim 12 wherein the curved bifurcated portions have different radii of curvature.

14. The intravaginal device of claim 1 wherein the guide rail is long enough to extend out of the patient when the distal, non-traumatic tip is disposed within the patient's cervical canal.

15. The intravaginal device of claim 1 wherein the tissue grasping mechanism is an arm which has a proximal end secured to the guide rail at a location proximal to the sound and a distal end with a tissue grasping element.

16. The intravaginal device of claim 15 wherein the tissue grasping element is a spike.

17. The intravaginal device of claim 16 wherein the distal end of the arm is biased away from the guide rail.

18. The intravaginal device of claim 15 wherein the guide rail has an outer sheath slidably disposed to move distally to engage the arm of the tissue grasping mechanism and drive the tissue grasping element on the distal end inwardly into engagement with tissue disposed between the guide rail and the tissue grasping element

19. The intravaginal device of claim 18 wherein the outer sheath has an independent proximal portion with proximal and distal ends, an independent distal portion with proximal and distal ends and a force transmitting connection between the distal end of the proximal portion and the proximal end of the distal portion to hold the proximal and distal portions together

20. The intravaginal device of claim 19 wherein the force transmitting connection includes a semicircular step on the distal end of the proximal portion and a semicircular step on the proximal end of the distal portion.

21. The intravaginal device of claim 18 wherein the sheath is configured to be locked in position so as to lock the arm in engagement with tissue.

22. The intravaginal device of claim 19 wherein the proximal portion of the outer sheath has a longitudinally oriented slot extending proximally from the distal end of the distal portion 21 wherein the guide rail has a locking pin configured to be received by the longitudinally oriented slot in the outer sheath.

23. The intravaginal device of claim 22 wherein the outer sheath is provided with a circumferentially oriented slot in communication with the longitudinally oriented slot which is configured to receive the locking pin on the guide rail and lock the sheath in position.

24. The intravaginal device of claim 19 wherein the proximal section of the guide rail is releasably connected to the distal section of the guide rail. outer sheath.

25. The intravaginal device of claim 15 wherein the proximal and distal shaft sections of the guide rail are releasably connected by a connecting rod.

26. The intravaginal device of claim 25 wherein the connecting rod has male threads on a distal end thereof.

27. The intravaginal device of claim 26 wherein the distal end of the distal shaft section has female threads configured to receive the male threads on the distal end of the connecting rod.

28. The intravaginal device of claim 25 wherein the distal end of the proximal shaft section of the guide rail has an inner shoulder configured to receive the proximal end of the distal shaft section.

29. The intravaginal device of claim 1 wherein the atraumatic distal tip of the guide rail has a length of about 1 inch to about 5 inches.

30. The intravaginal device of claim 29, wherein the atraumatic distal tip of the guide rail has a length of about 1.5 inches to about 2.5 inches.

31. The intravaginal device of claim 1, wherein the guide rail has a length of about 1 inch to about 12 inches.

32. The intravaginal device of claim 1, wherein the guide rail has a length of about 3 inches to about 6 inches.

33. The intravaginal device of claim 1, wherein the guide rail has a diameter of about 0.125 inch to about 0.25 inch.

34. A system for performing an intravaginal therapeutic or diagnostic procedure on a female patient having a uterine cervix and a cervical os, comprising:

- a) an intravaginal device for delivery of medical instruments, including:
  - i. an elongated guide rail which has an elongated shaft with a proximal section with a distal end and proximal end configured to extend out of the patient during the procedure and to allow for the mounting of a medical instrument thereon and with a distal section with a proximal end and a distal end configured for entry into a female patient's cervical canal and which is configured for intravaginal guidance of a medical instrument to the patient's uterine cervix; and
  - ii. a tissue grasping assembly comprising

- b) a first elongated member which has a proximal portion and a distal portion with a distal end secured to a distal section of the guide rail proximal to the distal end, and
- c) a second elongated member which has a proximal portion and a distal portion with a tissue grasping distal end and which is pivotally connected to the first elongated member at a pivot point thereon proximally spaced from the distal end of the first elongated member so that the tissue grasping distal end of the second elongated member grasps uterine cervical tissue against the guide rail on the same side of the guide rail to which the distal end of the first elongated member is secured when the distal tip of the guide rail is disposed within the patient's cervical canal; and
- d) a therapeutic or diagnostic medical instrument slidably disposed on the guide rail.

35. A system for performing an intravaginal therapeutic or diagnostic procedure on a female patient having a uterine cervix and a cervical os, comprising:

- a) an intravaginal device for delivery of medical instruments, including:
  - i. an elongated guide rail which has an elongated shaft with a proximal section with a distal end and proximal end configured to extend out of the patient during the procedure and to allow for the mounting of a medical instrument thereon and with a distal section with a proximal end and a distal end configured for entry into a female patient's cervical canal and which is configured for

intravaginal guidance of a medical instrument to the patient's uterine cervix; and

- ii. a tissue grasping assembly comprising an arm which has a proximal end secured to the guide rail at a location proximal to the sound and a distal end with a tissue grasping element and which is biased away from the guide rail; and

- b) a therapeutic or diagnostic medical instrument slidably disposed on the guide rail.

36. The system of claim 35 wherein the tissue grasping element is a spike.

37. The system of claim 35 wherein the guide rail has an outer sheath slidably disposed to move distally to engage the arm of the tissue grasping mechanism and drive the tissue grasping element on the distal end inwardly into engagement with tissue disposed between the guide rail and the tissue grasping element

38. A method of performing a therapeutic or diagnostic intravaginal procedure on a female patient having a uterine cervix and an accessible cervical os, comprising:

- a. providing a tenaculum-type device configured for intravaginal delivery having
  - i. an elongated guide rail which is configured to guide a medical instrument to a desired location within the patient's vaginal canal and which has a distal tip for insertion into the patient's cervical os; and
  - ii. a tissue grasping assembly which has a first elongated member having a distal section attached to the distal section of the guide rail

and a proximal section configured to extend out of the patient during the procedure and which has a second elongated member having a distal section with a distal end configured to grasp the patient's uterine cervix and a proximal section configured to extend out of the patient during the procedure to facilitate grasping the patient's uterine cervix;

- b. introducing the tenaculum-like device into the patient's vaginal canal and advancing the tenaculum therein until the atraumatic distal tip of the guide rail passes through the cervical os and is disposed at least in part within the patient's uterine cervix; and
- c. advancing a medical instrument over the guide rail within the patient's vaginal canal to perform a procedure therein.

39. The method of claim 38 wherein the medical instrument advanced over the guide rail is a uterine artery occlusion device.

40. An intravaginal tenaculum-like device for adjusting the position of a female patient's uterine cervix to facilitate intravaginal delivery of a therapeutic or diagnostic instrument, comprising:

- a. an elongated guide rail which has a proximal portion with a proximal end configured to extend out of the patient during the procedure and to allow for the mounting of a medical instrument thereon and a distal portion with a distal tip configured for entry into the patient's cervical canal and which is configured for intravaginal guidance of a medical instrument to the patient's uterine cervix; and



- b. a tissue grasping assembly comprising
  - i. a first elongated member which has a proximal section and a distal section with a distal end secured to a distal portion of the guide rail proximal to the atraumatic distal tip and
  - ii. a second elongated member which has a proximal section and a distal section with a tissue grasping element on the distal end and which is pivotally connected to the first elongated member at a pivot point thereon proximally spaced from the distal end of the first elongated member so that the tissue grasping element on the distal end of the second elongated member grasps the patient's uterine cervix on the same side of the guide rail to which the distal end of the first elongated member is secured when the distal tip is disposed within the patient's cervical canal.

41. The device of claim 40, further comprising a securing element configured to maintain the tissue grasping element in contact with tissue when the distal end of the guide rail is disposed within said cervical canal.

42. The device of claim 40, wherein the tissue grasping element has a sharp point.

43. The device of claim 40, wherein the guide rail is configured to receive a slidable coupling element attached to a medical device which is configured to move in a longitudinal direction along the guide rail to guide the medical device over the guide rail.

44. The device of claim 40, wherein a collar configured to move in a longitudinal direction is mounted on the guide rail.

45. The device of claim 44 wherein the guide rail has threads on an exterior portion thereof and the collar has internal threads configured to operatively engage with the exterior threads and rotation of the collar around a longitudinal axis of the guide rail is effective to provide longitudinal movement of the collar along the guide rail.

46. An intravaginal device for delivery of a medical instrument to a female patient's uterine cervix, related tissue or near-by anatomical structure, comprising:

- a. an elongated guide means which has a distal portion with a distal tip, which has a proximal portion with a free proximal end configured to receive and guide a medical instrument to the patient's uterine cervix, related tissue or near-by anatomical structure; and
- b. a tissue grasping means secured to the distal portion of the guide means configured to grasp the patient's uterine cervix[, related tissue or near-by anatomical structure] to facilitate delivery of the medical instrument over the guide rail to the patient's uterine cervix.

47. A method of treating a female patient for a uterine disorder, comprising:

- a. providing a tenaculum-type device configured for intravaginal delivery having
  - i. an elongated guide rail which has a distal tip configured for insertion into the patient's cervical os, and
  - ii. a tissue grasping assembly which has a distal with an elongated tissue grasping member secured to the elongated guide rail at a location proximal to the distal tip of the guide rail and configured to grasp the patient's uterine cervix and which has a proximal section

configured to extend out of the patient during the procedure to facilitate grasping the patient's uterine cervix;

- b. introducing the tenaculum-like device into the patient's vaginal canal and advancing the tenaculum-like device therein until the distal tip of the guide rail passes through the cervical os and is disposed at least in part within the patient's cervical canal; and
- c. advancing a uterine artery occlusion device with at least one clamping member over the guide rail within the patient's vaginal canal until the clamping member presses against the patient's vaginal fornix adjacent a uterine artery to be occluded; and
- d. pressing the clamping member of the uterine artery occlusion device against the vaginal fornix to at least partially occlude the uterine artery for at least an effective period of time to have a therapeutic effect on the patient's uterine disorder.

48. An intravaginal device for delivery of a medical instrument to a female patient's uterine cervix, related tissue or near-by anatomical structure, comprising:

- a. an elongated guide rail which has a distal portion with an expandable non-traumatic distal tip and which is configured to guide a medical instrument mounted thereon to the patient's uterine cervix, related tissue or near-by anatomical structure; and
- b. a tissue grasping mechanism secured to the distal portion of the guide rail configured to grasp the patient's uterine cervix to facilitate delivery of the medical instrument over the guide rail to the patient's uterine cervix.

49. An intravaginal tenaculum-type device for delivery of a medical instrument to a female patient's uterine cervix, related tissue or near-by anatomical structure, comprising an elongated guide rail which has a distal portion with an expandable non-traumatic distal tip and which is configured to guide a medical instrument mounted thereon.

50. The intravaginal device of claim 49 wherein the distal tip is expandable to snugly fit within the patient's cervical canal.

51. The intravaginal device of claim 50 wherein the expandable distal tip is split into bifurcated portions.

52. The intravaginal device of claim 51 wherein the bifurcated portions are curved.

53. The intravaginal device of claim 52 wherein the curved bifurcated portions have different radii of curvature.